Special 510K Summary

K060822

Submitter Contact Information:

Company Name/Address:	Keeler Instruments Inc 456, Parkway, Broomall, PA 19008
Company Phone No:	(610) 353 4350
Company Fax No:	(610) 353 7814
Contact Person:	Mr. Eugene VanArsdale (Marketing Director).
Manufacturing Location:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire. SL4 4AA. United Kingdom.
Company Phone No:	(44) 1753 857177
Company Fax No:	(44) 1753 830247
Contact Person:	Mr. Neil Atkins (Development Manager).

MAY 2 3 2006

Device Information:

Device Trade Name:	Vantage Plus Binocular Indirect Ophthalmoscope
Common Name:	Ophthalmoscope
Class:	II
Classification Panel:	86
Product Code:	HLI (AC) and HLJ (DC)
Regulation Number:	886.1570

Substantial Equivalence:

Predicate Device:	Vantage Binocular Indirect Ophthalmoscope.
510(k) No:	**K942104**
Manufacturer:	Keeler Ltd (FDA Registration No 1000391004) (Address as above).
Distributor:	Keeler Instruments Inc (FDA Registration No 2519784) (Address as above).

Device Description:

The Vantage Plus is a head mounted Binocular Indirect ophthalmoscope designed to be used by trained personnel for illuminating and viewing parts of the eye such as the Cornea and retina when used in conjunction with an ophthalmic lens.
The instrument has two main elements i) The illumination element ii) the viewing element.
The illumination element consists of a 6Volt, 5Watt Xenon filament lamp, a condensing lens, IR filtration, User filters for diagnostic purposes, variable stop sizes for increasing/decreasing light aperture sizes, a projection lens and an illumination mirror used by the user to direct the light.
The binocular Viewing element consists of low powered Viewing Lenses (+2 dioptre) and directional mirrors which are adjustable to obtain optimal views of the eye.
The unit has adjustable illumination levels and is powered by the same power sources to that used on the Vantage (Re: 510(k) K942104).
To improve the ease of use of the instrument, the Vantage Plus combines the Aperture selector control and the Viewing mirror adjustments to achieve optimal instrument setting with minimum fuss. This feature is not present on the Vantage (Re: 510(k) K942104).

Comparison of Technological Characteristics:

Comparison of Indirect Ophthalmoscope Technological Characteristics		
Criteria	**Predicate Device Keeler Vantage (Re:510(k) K942104)**	**Keeler Vantage Plus (see note 4)**
Type	**Binocular (Headband Mounted)**	**Binocular (Headband Mounted)**
Illumination	**6V, 10 Watt Halogen Filament Bulb**	**6V, 5 Watt Xenon Filament Bulb**
Safety Filter IR Blocker	**Selectable**	**Permanent**
Light Output (See note 1)	**954 Lux**	**913 Lux**
Blue Filter	**Selectable**	**Selectable**
Red Free Filter	**Selectable**	**Selectable**
Diffuser	**Selectable**	**Selectable**
Light aperture sizes (See note 2)	**Large (60mm)**	**Large (60mm) +/-5%**
	Medium (45mm)	**Medium (45mm) +/-5%**
	Small (22mm)	**Small (22mm)+/-5%**
Inter Pupillary Distance Adjustment	**52mm to 76mm**	**48mm to 76mm**
Lens Power Viewing Optics	**+2 Dioptre**	**+2 Dioptre**
Attachments	**Hi-Mag**	**Hi-Mag**
	Teaching Mirror	**Teaching Mirror**
Power Sources (See Note 2)	**Wall Pack**	**Wall Pack**
	Smart Pack	**Smart Pack**
	Wireless battery Pack	**Wireless Battery Pack**
Note 1: Average light output from a selection of bulbs for a patch size of 60mm. Note 2: Measurements taken from 440mm from the front of the instrument. Note 3: All Power supplies comply with relevant parts of BS EN 60601-1 and 60601-1-2. Note 4: All testing has been carried out on a fully functional prototype.		

Quality approvals: Keeler is an ISO 9001:2000 and BS EN 13485:2003 compliant company and are obliged to ensure that our operating and design practices fully comply. As part of the design process, all necessary risk analysis, risk management, design verification and validation are conducted to ensure that the safety and effectiveness of product designs either meet or surpass the product specification and comply too the relevant standards.

Risk Management: Completed as per BS EN ISO 14971:2001

Light Hazard: The Vantage Plus has been tested in accordance with BS EN ISO 15004:1998 and is within the limits specified for ***Optical radiation Hazard (Section 6.3)*** (See separate report under Technical Documentation).

Electrical: The Vantage Plus is using the same Power Sources as the Vantage detailed in 510(k) **K942104.** All power sources are compliant with BS EN 60601-1 and 60601-1-2 and Keeler has not received any adverse reports on these products (See separate reports under Technical Documentation).

Explosion: Low probability. All measures have been taken to reduce the risk of explosion by using non-explosive materials, ensuring the product meets all of the relevant electrical safety requirements and detailed user instructions defining the requirements for safe usage of the instrument.

Fire Hazard: Low Probability. All measures have been taken to use self extinguishing materials which are either HB or VO rated. The system is illuminated using a 5watt Xenon lamp and all materials used in the vicinity are specifically designed to operate in high temperature environments safely.

Surface Temperature: Complies with BS EN ISO 60601-1 for temperature of external surfaces and controls. Caution in user instructions indicates '*Do not remove bulb whilst hot*'.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2008

Keeler Instruments, Inc.
c/o Mr. Eugene VanArsdale
Marketing Director
456 Parkway
Broomall, PA 19008

Re: K060822
Trade/Device Name: Vantage Plus Binocular Indirect Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: HLI and HLJ
Dated: May 4, 2006
Received: May 8, 2006

Dear Mr. VanArsdale:

This letter corrects our substantially equivalent letter of May 23, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Copy

Indications for Use

510(k) Number (if known):

Device Name: Vantage Plus Binocular Indirect Ophthalmoscope

Indications for Use:

The Keeler Vantage Plus Indirect Ophthalmoscope is intended to be used to examine the Cornea, aqueous, lens, vitreous and retina of the eye.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K060822